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10/561,572	12/19/2005	Kalford C. Fadem	0103701.0523541	3497
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EXAMINER NGUYEN, HUONG Q				
ART UNIT		PAPER NUMBER		
3736				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary

Application No.

10/561,572

Applicant(s)

FADEM, KALFORD C.

Examiner

HELEN NGUYEN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 1/5/2010. Claims 1, 11, 23, 24, and 30 are amended, overcoming the previous claim objections. **Claims 1-32** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-3, 11, 13-19, 21-25, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al (US Pat No. 5954667) in view of John et al (US Pub No. 20010049480).

4. In regards to **Claim 1**, Finkenzeller et al disclose a screening device, comprising: a frame 10 shaped to be engageable to a head between a reference location, at least one ear and a signal detection location; a reference electrode 22 attached to the frame at the reference location; a signal electrode 21 attached to the frame at the signal detection location; an auditory signal producer 30 positioned by the frame over the ear; and an auditory evoked response (AER) data processor 1 operably configured to initiate an auditory signal from the auditory signal producer and to perform a signal processing operation on an AER signal sensed across the reference and signal electrodes, best seen in Figure 1-2.

5. However, Finkenzeller et al do not disclose a diagnostic analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a diagnostic analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a diagnostic analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, as taught by John et al, to effectively determine the presence of a neurological condition.

6. **Claim 2:** Finkenzeller et al disclose a cantilevered flexible arm 12 connecting the signal electrode 21 to the frame 10, best seen in Figure 1.

7. **Claim 3:** Finkenzeller et al disclose a second signal electrode 21 attached to the frame, best seen in Figure 2.

8. **Claim 11:** Finkenzeller et al in combination with John et al disclose the at least one predetermined AER characteristic is capable of comprising a dyslexic AER characteristic.

9. **Claim 13:** Finkenzeller et al disclose the AER data processor 1 comprises a control module integral to the frame (Col.4: 65-67).

10. **Claim 14:** Finkenzeller et al disclose the frame 10 includes a disposable portion that includes the electrodes 21, 22.

11. **Claim 15:** Finkenzeller et al disclose the AER data processor 1 necessarily includes digital storage configured to store the AER data.

12. **Claim 16:** Finkenzeller et al disclose the AER data processor 1 is necessarily operably configured to perform a sequence of screening tests, and to store in the digital storage AER data associated with each test.

13. **Claim 17:** Finkenzeller et al disclose the digital storage further includes a predetermined test protocol.

14. **Claim 18:** Finkenzeller et al disclose the AER data processor 1 is further operably configured to generate a user indication of a test condition.

15. **Claim 19:** Finkenzeller et al disclose the frame 10 is operably shaped to connect between the ears across a front portion of a patient's head, best seen in Figure 1-2.

16. **Claim 21:** Finkenzeller et al disclose the frame 10 comprises an ear cup 30 having a resilient portion inwardly affixed thereto, best seen in Figure 1-2.

17. **Claim 22:** Finkenzeller et al disclose the frame 10 further comprises an ear cup 30 having an electrode 21 registered caudad to the sylvian fissure of a subject, best seen in Figure 1-2.

18. In regards to **Claim 23**, Finkenzeller et al disclose a method of performing auditory evoked response (AER), comprising: positioning a device, best seen in Figure 1-2 on the head of a subject, the device positioning a sound producer 30, a reference electrode 22 and a signal electrode 21; generating an auditory stimulus; and recording AER data across the reference and

signal electrodes with signal generator/evaluation unit 1 (Col.3: 59-65). However, Finkenzeller et al do not disclose a data analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a data analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (§0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a data analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic after connecting the device to the data analyzer, as taught by John et al, to effectively determine the presence of a neurological condition.

19. **Claim 24:** Finkenzeller et al in combination with John et al disclose recording the AER data further comprises necessarily storing the AER data on the device; transmitting the stored AER data to the data analyzer.

20. **Claim 25:** Finkenzeller et al disclose positioning the device on the head of the subject further comprising positioning the subject face up and positioning the device across a forward portion of the subject's head, best seen in Figure 1-2.

21. **Claim 27:** Finkenzeller et al disclose necessarily detecting a resting brain wave and initiating the auditory stimulus at a predetermined slope of the resting brain wave.

22. **Claims 4-6, 8-10, and 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al, further in view of Lencioni, Jr (US Pat No. 4219028).

23. In regard to **Claims 4-6 and 30-32**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose the use of a multiplexing channel. Lencioni, Jr teaches that a multiplexing channel 18, 20 is effectively used to assign the electrodes of a device to enable proper sampling of the desired electrode in turn (Col.1: 21-22; Col.5: 21-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John et al include a multiplexing channel as taught by Lencioni, Jr to effectively enable the AER data processor to selectively sample from the first and second signal electrodes, wherein it is obvious that the electrodes can be sampled at any desired frequency such as sampling the first signal electrode at a low frequency sampling rate and sampling the second signal electrode at a high frequency.

24. In regard to **Claims 8-10**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose associating a test subject identification with the AER signal. Lencioni, Jr teaches that a test subject identification is associated with a sampled electrode signal to effectively enable distinction of the test results for each individual test subject (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al as modified by John et al to

have a test subject identification associated with the AER signal as taught by Lencioni, Jr, wherein it is well known to a skilled artisan that a test subject identification device may comprises known means such as a barcode scanner or a radio frequency identification scanner, to effectively enable distinction of the AER signal for different test subjects.

25. **Claims 7 and 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al.

26. In regards to **Claim 7**, Finkenzeller et al in combination with John et al disclose the invention above as claimed including teaching that the complete device may be mounted on the frame (Col.4: 65-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a flexible printed circuit harness containing the electrodes and communication paths to the AER data processor which is well known to one skilled in the art as an effective circuit and electrode structure to effectively have all components of the device mounted onto the frame and shaped for conforming to the head under the resilient urging of the frame.

27. In regards to **Claim 20**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose a pair of ear cups attached to each end of the frame. However, Finkenzeller et al teach that the device can be advantageously used for both the left and right ears by rotating the device to position ear cup 30 accordingly (Col.3: 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

was made to have a pair of ear cups attached to each end of the frame to effectively enable use of both the left and right ears without having to reposition the device.

28. **Claims 12 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al, further in view of Zoth et al (US Pat No. 6786873).

29. In regards to **Claim 12**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose the diagnostic analyzer is coupled to the frame via a communication link. Zoth et al teach the advantages of a communication link to remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the diagnostic analyzer coupled to the frame of Finkenzeller et al as modified by John et al via a communication link as taught by Zoth et al as an effective means to transfer data between the two.

30. In regards to **Claim 29**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose accessing a remotely stored auditory testing protocol into the device. Zoth et al teach the advantages of a communication link to remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John

et al access remotely stored data such as an auditory testing protocol as taught by Zoth et al to effectively enable access of necessary data into the device for testing.

31. **Claims 26 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al above, further in view of John (US Pub No. 20050018858).

32. Finkenzeller et al in combination with John et al (2001) disclose the invention above as claimed but do not disclose imposing a sampling delay. John et al (2005) teach that a sampling time delay is effective when sampling the AER signal to prevent undue noise in the signal (§0076). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to impose a sampling delay during the sampling process of Finkenzeller et al as modified by John et al (2001) as taught by John et al (2005) to effectively lessen the effects of noise or artifacts into the epochs of sampled AER data.

Response to Arguments

33. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/561,572
Art Unit: 3736

Page 11

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Examiner, Art Unit 3736

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